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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Doris HUBLER et al.

Group Art Unit 1614

Serial No.: 10/798,780

Examiner: unknown

Filed: March 12, 2004

For: METHODS AND PHARMACEUTICAL COMPOSITIONS FOR RELIABLE  
ACHIEVEMENT OF ACCEPTABLE SERUM TESTOSTERONE LEVELS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees



Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:



within three months of the filing date of a national application other than a CPA under § 1.53(d);



within three months of the actual filing date of the national phase of a PCT application; OR



before the mailing of a first substantive office action (including after filing of an RCE).



Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:



a final rejection under 37 C.F.R. 1.113;



termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2);  
OR



a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
  - ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
- ☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:
- ☐ a final action under 37 C.F.R. § 1.113;
  - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - ☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was a first cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☒ Copies of materials listed were cited in an international search report dated December 10, 2003 and May 28, 2004.
- ☐ Copies of the materials listed are attached.

### Non-English Language References

- ☒ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
- X = document of particular relevance when it is taken alone  
Y = document of particular relevance when it is combined with another such document  
A = document defining the general state of the art  
O = non-written disclosure  
P = intercalated document  
T = document cited to understand the theory or principle underlying the invention  
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date  
D = cited in the application  
L = cited for another reason  
& = publication of member of same patent family
- ☐ Translation of other relevant information on foreign search report

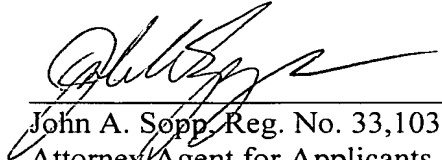
### Other Information

#### Payment of Fees Due (If Any):

- ☐ A check for \$\_\_\_\_\_ covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

  
\_\_\_\_\_  
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Attorney/Agent for Applicants

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Attorney Docket No. PLOVIN-0010

Date: August 10, 2004

JAS/rrt

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	2
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**Complete if Known**

Application Number	10/798.780
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Filing Date	March 12, 2004
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First Named Inventor	Doris HUBLER
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Group Art Unit	1614
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Examiner Name	Unassinged
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Attorney Docket Number	PLOVIN-10
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## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]Examiner  
Signature

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark if the English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

### Complete if Known

Application Number	10/798,780
Filing Date	March 12, 2004
First Named Inventor	Doris HUBLER
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	PLOVIN-10

### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Database WPI, Section Ch. Week 199524, Derwent Publications Ltd., London, GB, Class B01, AN 1995-185577 XP002264337	
		Wang Lie-zhen, Wang et al., The Therapeutic Effect of Domestically Produced Testosterone Undecanoate in Klinefelter Syndrome (Abstract)	
		Zhao-dian, Chen et al., "Clinical Study of Testosterone Undecanoate Compound on Male Contraception", First Affiliated Hospital of Zhejiang Medical University, (Abstract)	
		Zhang, Gui-Yuan, et al., "A Pharmacokinetic Study of Injectable Testosterone Undecanoate in Hypogonadal Men", Journal of Andrology, Vol. 19, No. 6, November/December (1998), pgs. 761-768	
		Zhang, Gui-Yuan, et al., "A Clinical Trial of Injectable Testosterone Undecanoate as a Potential Male Contraceptive in Normal Chinese Men", The Journal of Clinical Endocrinology & Metabolism (1999)	
		Behre, H.M. et al., "Intramuscular Injection of Testosterone Undecanoate for the Treatment of Male Hypogonadism: Phase I Studies", European Journal of Endocrinology, 140, pgs. 414-419, (1999)	
		Von Eckardstein, Sigrid, et al. "Treatment of Male Hypogonadism with Testosterone Undecanoate Injected at Extended Intervals of 12 Weeks: A Phase II Study", Journal of Andrology, Vol. 23, No. 3, May/June 2002	
		Incomplete Search Report dated 12/10/03	
		European Search Report dated 5/28/04	

Examiner  
Signature

Date  
Considered

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